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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,269	07/11/2001	Asa Berglund	003300-790	2429
21839	7590	10/20/2003	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			SEHARASEYON, JEGATHEESAN	
POST OFFICE BOX 1404			ART UNIT	
ALEXANDRIA, VA 22313-1404			PAPER NUMBER	
			1647	13

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Applicati n N . 09/869,269	Applicant(s) BERGLUND, ASA	
	Examiner Jegatheesan Seharaseyon	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-16 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants election of xanthine and its derivatives as an enhancing agent and cyclic amides for the solvent and a combination of both with traverse in Paper No: 13 (7/3/03) is acknowledged. The traversal is on the ground(s) that the Office has required the Applicant to elect an enhancing agent and an organic solvent treating them separately. This Applicant asserts is inappropriate with regard to what is claimed. In addition, the Applicant also alleges that the compounds of the invention are both structurally and functionally related. This is not found to be persuasive because the Office set for the restriction based on Applicants claim presentation and required that the Applicant elect a single species of enhancing agent and organic solvent for examination of claims. In addition, Applicant was required to elect a single species of enhancing agent and organic solvent because contrary to Applicants assertion the compounds listed are different from each other. For example, Applicant is using both xanthine derivatives and pyrimidinol derivatives as enhancing agents in the claims. Furthermore, Applicant is also reciting various organic solvents such as ketones, amides etc. The searches for each of the compounds are not extensive and would be a burden on the Office to search all of the compounds. Therefore, the species election requirement is deemed proper and made FINAL. Claims 1-20 are pending.

2. Claims 6, 7, 17, 18 and 19 are withdrawn as they are directed to un elected inventions.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8-16 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3a. Claim 1 is rejected as vague and indefinite in its lack of recitation of the precise number and the order of adding enhancing agents and organic solvents to induce the production of interferon. It is also unclear if these compounds need to be added in any particular order etc. Claims 2-5, 8-16 and 20 are rejected insofar as they are depended on rejected claim 1.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4a. Claims 1-5 and 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goren et al. (1986) in view of Zahorska et al. (1995).

The instant invention is directed to the induction of interferon- α production using various enhancing agents.

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Goren et al. teach a process to produce interferon- α in human monocyte and lymphocytes. They have used human peripheral blood lymphocytes and monocytes to produce interferon- α by inducing them with Sendai virus (Page: 323, Introduction). However, Goren et al. do not describe the use of xanthine and its derivatives for the increased induction of the interferon.

Zahorska et al. teach the increased production of interferon in the presence of theophylline (Page: 43, Abstract). Theophylline is a xanthine derivative. Interferon production was induced by poly I: C in the presence of DEAE dextran (Page: 44, Materials and Methods). Theophylline was added to cell cultures for up to 6 hours starting 2h after interferon induction (Page: 44, Materials and Methods).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to enhance the interferon production following the induction with virus of human monocyte and lymphocytes, as described by Zahorska, because Zahorska teaches that the addition of Theophylline, a xanthine derivative increase the production of interferon. One of ordinary skill in the art would have been motivated to increase the production of interferon in order to be used as antiviral and anticancer drug. Thus the claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary. Therefore, the instant invention is obvious over Goren et al. (1986) in view of Zahorska et al. (1995).

4b. Claims 8, 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goren et al. (1986) and in view of Johnston (U.S. Patent No: 4,780,413).

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The instant invention is directed to the induction of interferon- α production using various enhancing agents.

The teaching of Goren et al. have been described above in 4a. However, Goren et al. do not describe the use of cyclic amides such as pyrrolidinones for the increased induction of interferon.

Johnston teaches the use pyrrolidinones and other cyclic amides for enhancing the production of interferon in cells infected with Sendai virus. (columns 3 and 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to enhance the interferon production following the induction with virus of human monocyte and lymphocytes, as described by Johnston , because Johnston teaches that the addition of pyrrolidinones, a cyclic amide increase the production of interferon. One of ordinary skill in the art would have been motivated to increase the production of interferon in order to be used as antiviral and anticancer drug. Thus the claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary. Therefore, the instant invention is obvious over Goren et al. (1986) in view of Johnston (U.S. Patent No: 4,780,413).

5. Claims 1-5, 8-16 and 20 are rejected over prior art.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name.

**LORRAINE SPECTOR
PRIMARY EXAMINER**